



Billing Code: 4120-01-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

**[CMS-3387-PN]**

#### **Medicare and Medicaid Programs; Application from The Compliance Team (TCT) for Initial CMS Approval of its Diabetes Outpatient Self-Management Training Accreditation Program**

**AGENCY:** Centers for Medicare and Medicaid Services, HHS.

**ACTION:** Notice with request for comment.

**SUMMARY:** This proposed notice acknowledges the receipt of an application from The Compliance Team for initial recognition as a national accrediting organization for accrediting entities that wish to furnish diabetes outpatient self-management training services to Medicare beneficiaries.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [Insert date 30 days after date of publication in the **Federal Register**].

**ADDRESSES:** In commenting, please refer to file code CMS-3387-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address **ONLY**:

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-3387-PN,  
P.O. Box 8010,  
Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-3387-PN,  
Mail Stop C4-26-05,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the “SUPPLEMENTARY INFORMATION” section.

**FOR FURTHER INFORMATION CONTACT:**

Christina Mister-Ward, (410) 786-2441.

Shannon Freeland, (410) 786-4348.

Lillian Williams, (410) 786-8636.

**SUPPLEMENTAL INFORMATION:**

Inspection of Public Comments: All comments received before the close of the comment period

are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov> . Follow the search instructions on that website to view public comments.

## **I. Background**

Diabetes outpatient self-management training services is defined at section 1861(qq)(1) of the Social Security Act (the Act) as “educational and training services furnished (at such times as the Secretary determines appropriate) to an individual with diabetes by a certified provider (as described in paragraph (2)(A)) in an outpatient setting by an individual or entity who meets the quality standards described in paragraph (2)(B), but only if the physician who is managing the individual's diabetic condition certifies that such services are needed under a comprehensive plan of care related to the individual's diabetic condition to ensure therapy compliance or to provide the individual with necessary skills and knowledge (including skills related to the self-administration of injectable drugs) to participate in the management of the individual's condition.”

In addition, section 1861(qq)(2)(A) of the Act describes a “certified provider” as a physician, or other individual or entity designated by the Secretary of the Department of Health and Human Services (the Secretary), that, in addition to providing diabetes outpatient self-management training services, provides other items or services for which payment may be made under this title. Section 1861(qq)(2)(B) of the Act further specifies that a physician, or such other individual or entity, must meet the quality standards established by the Secretary, except that the physician or other individual or entity shall be deemed to have met such standards if the

physician or other individual or entity meets applicable standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who participated in the establishment of standards by such Board, or is recognized by an organization that represents individuals (including individuals under this title) with diabetes as meeting standards for furnishing the services.

The statute also permits diabetes outpatient self-management training service programs to be deemed to have met Medicare regulatory quality standards if they are accredited by an organization approved by the Centers for Medicare & Medicaid Services (CMS). A national accrediting organization (AO) must have an agreement in effect with the Secretary and meet the standards and requirements specified in 42 CFR part 410, subpart H, to qualify for deeming authority. Our regulations pertaining to the application procedures to be an approved national accreditation organization for diabetes outpatient self-management training are specified at §410.142 (CMS process for approving national accreditation organizations). A national accreditation organization applying for deeming authority must provide us with reasonable assurance that the AO requires accredited entities to meet CMS' quality standards, the National Standards for Diabetes Self-Management Education and Support standards, or alternative requirements that meet or exceed our requirements that have been developed by a national accreditation organization and approved by CMS. (See §410.144 Quality standards for deemed entities.) We may approve and recognize a nonprofit organization with demonstrated experience in representing the interests of individuals with diabetes to accredit entities to furnish training. The national accreditation organization, after being approved and recognized by CMS, may accredit an entity to meet one of the sets of quality standards in §410.144 (Quality standards for deemed entities).

## **II. Approval of Accreditation Organizations**

Section 1865(a)(2) of the Act and §410.142 require that our findings concerning review and approval of a national AO's requirements consider, among other factors, the applying AO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data for validation.

Section 1865(a)(3) of the Act and §410.142(d) require that we publish, within 60 days after receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. Section 1865(a)(3)(A) of the Act further states, we have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of The Compliance Team's (TCT's) initial request for CMS approval of its diabetes outpatient self-management training accreditation program. This notice also solicits public comment on whether TCT's requirements meet or exceed the Medicare conditions for certification for diabetes outpatient self-management training services.

## **III. Evaluation of Deeming Authority Request**

TCT submitted all the necessary materials to enable us to make a determination concerning its request for initial CMS approval of its diabetes outpatient self-management training accreditation program. This application was determined to be complete on

July 27, 2019. Under section 1865(a)(2) of the Act and our regulations at §410.142, our review and evaluation of TCT will be conducted in accordance with our regulations, including:

- The requirements and quality standards TCT uses to accredit entities to furnish training.

- TCT's accreditation process to determine the following:

- ++ Frequency of accreditation.

- ++ Copies of accreditation forms, guidelines, and instructions to evaluators.

- ++ The accreditation review process and the accreditation status decision making process.

- ++ The procedures used to notify a deemed entity of deficiencies in its diabetes outpatient self-management training program and procedures to monitor the correction of those deficiencies.

- ++ The procedures used to enforce compliance with the accreditation requirements and standards.

- ++ Detailed information about the individuals who perform evaluations for the organization.

- ++ A description of the organization's data management and analysis system for its accreditation activities and decisions, including reports, tables, and other displays generated by that system.

- ++ A description of the organization's procedures for responding to and investigating complaints against an approved entity, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsmen programs, and CMS.

++ A description of the organization's policies and procedures for withholding or removing a certificate of accreditation for failure to meet the organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

++ A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that will serve as a basis for accreditation if CMS approves the organization.

++ A list of all of the approved entities currently accredited to furnish training and the type, category, and expiration date of the accreditation held by each of them.

++ The name and address of each person with an ownership or control interest in the organization.

++ Documentation that demonstrates its ability to furnish CMS with electronic data in CMS-compatible format.

++ A resource analysis that demonstrates that its staffing, funding, and other resources are adequate to perform the required accreditation activities.

++ A statement acknowledging that, as a condition for approval and recognition by CMS of its accreditation program, it agrees to comply with the requirements set forth in §§410.142 through 410.146.

++ Additional information CMS requests to enable it to respond to the organization's request for CMS approval and recognition of its accreditation program to accredit entities to furnish training.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

#### **IV. Collection of Information Requirements**

This document does not impose information collection and requirements, that is, reporting, recordkeeping or third party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### **V. Response to Comments**

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the “DATES” section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.



Dated: September 6, 2019.

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**Seema Verma,**

Administrator,

Centers for Medicare & Medicaid Services.